Advisory Committee for Pharmaceutical Science
Meeting May 7 - 8, 2002

Day 1: May 7

Draft Guidance: Food Effect BE Studies
CDER Guidance for Industry. Food effect bioavailability and fed bioequivalence studies: Study design, data analysis, and labeling. Draft Guidance. October 2001.

Biopharmaceutical Classification System
Amidon, Gordon, H. Lennernas, V Shah, and J Crison. A theoretical basis for a biopharmaceutic drug classification: The correlation of *in vitro* drug product dissolution and *in vivo* bioavailability. *Pharmaceutical Research* 12:413-420. 1995.

CDER Guidance for Industry: Waiver of in vivo bioavailability and bioequivalence studies for immediate-release solid oral dosage forms based on a biopharmaceutics classification system. August 2000.

Hussain, Ajaz. Biopharmaceutics Classification System (BCS): A Regulatory Risk Management Tool. Power Point presentation. February 7, 2002

Yu, Lawrence, et al. Biophramaceutics Classification System: The scientific basis for biowaiver extensions. Submitted to Pharmaceutical Research. March 19, 2001.

Yu, Lawrence, et al. Influence of drug release properties of conventional solid dosage forms on the systemic exposure of highly soluble drugs. AAPS PharmSci. 3(3) article 24. September 8, 2001.

Day 2: May 8

Process Analytical Technology Subcommittee
Hussain, Ajaz. The Subcommittee on Process Analytical Technologies (PAT) Closing Remarks. Power Point slides. February 26, 2002.

Chemometric Working Group - Recommendations and Summary of Discussion. Power Point presentation at PAT Subcommittee Meeting. February 25-26, 2002.

Product and Process Working Group - Summary of Discussion. Power Point presentation at PAT Subcommittee Meeting. February 25-26, 2002.

Process Analytical Technologies (PATs), Applications and Benefits Working Group - Summary of Discussion. Power Point presentation at PAT Subcommittee Meeting. February 25-26, 2002.

Process and Analytical Validation Working Group - Summary of Discussion. Power Point presentation at PAT Subcommittee Meeting. February 25-26, 2002.

Rapid Microbial Testing

Lewandoski, N. Is there time for rapid micro? Pharmaceutical Formulation and Quality. April/May 2001. pp. 17-22.

Reynolds, D. T. and C. R. Fricker. Application of laser scanning for the rapid and automated detection of bacteria in water samples. J. Appl. Micro. Vol. 86 pp. 785-795. 1999.

Wallner, G. et al. The ChemScan system:a new method for rapid microbiological testing of water. European Journal of Parenteral Science. Vol 2 No. 4 pp. 123-126. 1997.

Blend Uniformity

CDER Guidance for Industry. ANDAs:Blend uniformity analysis. Draft Guidance, August 1999.

Boehm, Garth et. al. Results of statistical analysis of blend and dosage unit content uniformity data obtained from the Product Quality Research Institute Blend Uniformity Working Group data-mining effort. Unpublished. March 2002.

PQRI Blend Uniformity Working Group. The use of stratified sampling of blend and dosage units to demonstrate adequacy of mix for powder blends. Unpublished. March 2002.

PQRI Steering Committee. Letter to Janet Woodcock, MD, Director CDER. dated March 28, 2002

Regulatory Issues - Polymorphism

Decision Tree #4: Investigating the need to set acceptance criteria for polymorphism in drug substances and drug products. in ICH Q6A page 83055 (see below).

International Conference on Harmonization; Guidance on Q6A Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances. Federal Register Vol 65:21 pages 83041-83063. December 29, 2000

Particle Size and Polymorph of Drug Substance - Summary Slides. Power Point presentation at AAPS Workshop - Drug Substance and Drug Product Specifications March 18-20, 2002.

Holcombe, Frank. Issues of Polymorphism and Abbreviated New Drug Applications. April 8, 2002.

Example of CDER's response to a Citizen's Petition. February 15, 2002.

Holcombe, Frank. Agency Position on Polymorphism and Abbreviated New Drug Applications. April 8, 2002.

CDER OIT. Approved Drug Products. Preface 21st Edition. 2001 pages v - viii.

USP. Chloramphenicol Palmitate Oral Suspension monograph.

USP. Idarubicin Hydrochloride exerpt from monograph.

CDER Guidance for Industry. Guideline for submitting supporting documenation in drug applications for the manufacture of drug substances. pages 44-48. February 1987.